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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/450,880	11/29/1999	DOUGLAS A. CRAIG	56376/JPW/AD	8284

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	PAPER NUMBER
1634	12

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/450,880	Applicant(s) CRAIG, DOUGLAS A.	
	Examiner Frank W Lu	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

1. The request filed on August 15, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/450,880 is acceptable and a CPA has been established. The claims pending in this application are claims 1-24. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn. An action on the CPA follows.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating human urinary incontinence with compound 1 or compound 2

which can activate human 5-HT_{1F} receptor (for the name of compounds, see page 17 of the specification), does not reasonably provide enablement for treating human urinary incontinence with any kind of 5-HT_{1F} receptor agonist which can activate the human 5-HT_{1F} receptor at least 10 fold more than it activates one of the receptors as recited in claims 1-24. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification show that: (1) any kind of 5-HT_{1F} receptor agonist which can activate the human 5-HT_{1F} receptor at least 10 fold more than it activates one of the receptors as recited in claims 1-24 can treat human urinary incontinence; and (2) any kind of 5-HT_{1F} receptor agonist can bind to the receptors as recited in claims 1-24. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether any kind of 5-HT_{1F} receptor agonist which can activate the human 5-HT_{1F} receptor at least 10 fold more than it activates one of the receptors as recited in claims 1-24

can treat human urinary incontinence and whether any kind of 5-HT_{1F} receptor agonist can bind to the receptors as recited in claims 1-24.

The invention relates to a method of treating urinary incontinence in human subject which comprises administering to a human subject a therapeutically effective amount of a 5-HT_{1F} receptor agonist which can activate the human 5-HT_{1F} receptor. The specification (see pages 22-24) show that rat urinary incontinence in the DIRC model can be treated with compound 1 or compound 2 (for the name of compounds, see page 17 of the specification) and this suggest human urinary incontinence can be treated with compound 1 or compound 2 (see applicant's declaration under 37 CFR 1.132 filed on April 29, 2002). Although the examiner agrees with applicant that 5-HT_{1F} receptor agonists are well known in the art (see page 5 of applicant's remarks filed on April 29, 2002), it is unclear whether any kind of 5-HT_{1F} receptor agonist which can activate the human 5-HT_{1F} receptor at least 10 fold more than it activates one of the receptors as recited in claims 1-24 can be used to treat human urinary incontinence. Specifically, it is unclear whether any kind of 5-HT_{1F} receptor agonist can bind to the receptors as recited in claims 1-24.

Clearly, there will be a lot of unpredictable factors when the skilled artisan uses the claimed method to treat human urinary incontinence and the skilled artisan will have no way to predict the experimental results. Such efforts constitute undue experimentation. The undue experimentation at least includes to test: (1) whether any kind of 5-HT_{1F} receptor agonist which can activate the human 5-HT_{1F} receptor at least 10 fold more than it activates one of the receptors as recited in claims 1-24 can be used to treat human urinary incontinence; and (2) whether any kind of 5-HT_{1F} receptor agonist can bind to the receptors as recited in claims 1-24.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-24 are rejected as vague and indefinite because claims 2-24 lack insufficient antecedent basis for the limitation recited in claim 1. Note that claims 1 only has seven different 5-HT receptors (1A, 1D, 2A, 3, 4, and 7). However, claims 2-24 have the receptors which do not recite in claim 1. Please clarify.

Response to Arguments

7. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. No claim is allowed.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94

(December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
November 7, 2002

ETHAN C. WHISENANT
PRIMARY EXAMINER